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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/540,963	03/31/2000	Thomas S. Kupper	B0801/777170 (JRV)	2087

7590 10/24/2003

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/540,963	KUPPER ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *13 August 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached sheets.*.

6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1,5 7,12 14,18-21,25,28-30,36,37 and 48*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

ATTACHEMENT TO ADVISORY ACTION

5. CONT. Applicant's arguments and amendments do not overcome the grounds of rejection of the claims under 35 U.S.C. 112, first paragraph, of record. The amendments, while overcoming a portion of the rejection of record dealing with the types of tissues to be targeted does not overcome the following issues of record: 1) the lack of enablement for targeting dendritic cells to lymphoid or non-lymphoid tissues which express a selectin ligand by transfecting the dendritic cells with an expression vector encoding any selectin other than an E/L-selectin chimera which contains the transmembrane and intracellular domains of L-selectin and the extracellular domain of E-selectin, 2) the lack of enablement for generating therapeutic or antigen-specific immune responses *in vivo* wherein the dendritic cells have not been pulsed with or transfected to express antigen. As previously noted, the specification does not teach any purpose for directing the dendritic cells to tissues or secondary lymph nodes other than for the vaccination against disease, particularly cancer. Further, while the applicant has deleted the word "vaccine" in the claims, the intended use of the claimed composition is clearly disclosed in the specification as treatment of cancer. The applicant's response does not provide any alternative use for generating antigen-specific immune responses other than disease treatment. Regarding 1), the previous office actions noted that the specification's working examples clearly demonstrate that the transduction of dendritic cells with an retrovirus encoding L-selectin did **not** result in expression of L-selectin on the dendritic cell surface (specification, page 28, lines 1-4). While the previous office action noted that the specification references a publication which teaches a non-cleavable form of L-selectin, the specification does not provide any evidence that dendritic cells can be modified to express a non-cleavable form of L-selectin or that expression of such a modified L-selectin would be capable of mediating dendritic cell homing to peripheral lymph nodes *in vivo*. The applicant's working example, as discussed above, utilizes a chimeric E/L selectin wherein the endothelial binding portion is derived from E selectin. Aside from this single working example , the applicant's data does not demonstrate or suggest that wild type L, E, or P-selectin can be used to effectively target dendritic cells to lymphoid or non-lymphoid tissue in vivo, or that any chimeric or mutated L, E, or P-selectin other than the chimeric E/L selectin is capable of targeting dendritic cells to peripheral lymph nodes or any other selectin expressing tissue *in*

vivo. Please note as well, see section 6., that the post-filing reference by von Andrian et al. has not been considered since it is not directed solely to issues newly raised in the final office action. Therefore, for reasons of record, the rejection stands.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 872-9306.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER